Over-the-Counter Hearing Aid Act

MYTH vs. FACT

MYTH: Patients can't safety self-diagnose. There is no way to self-assess hearing loss.

- In 2016, the FDA approved an over-the-counter hearing test called iHear (which sells online for $69). According to iHear Medical, the iHearTest is a hearing screener for profiling hearing ability based on the World Health Organization (WHO) guidelines, targeting adults who suspect they have hearing loss, or those reluctant to seek professional evaluation for a basic hearing assessment.
- According to the Doctors of Audiology, "the risk of non-treatment may be greater than the risk of treatment."
- Several European countries have demonstrated successful use of telephone screenings.[1]

MYTH: Patients can't self-fit their own OTC hearing aids; they need help from an audiologist.

- The first ever NIH-funded randomized placebo controlled trial of OTC hearing aids showed that participants derived equal benefit from hearing aids whether they were fitted by audiologists or chosen by the users on their own.[2]

MYTH: We should only provide OTC hearing aids for mild hearing loss (versus "mild to moderate" loss.)

- In the last two years, though, both the President's Council of Advisors on Science and Technology and a National Academy of Sciences report called for the F.D.A. to establish an over-the-counter category FOR "mild to moderate" hearing loss.
- Leaving out those individuals with moderate hearing loss would mean that fewer people who benefit from the OTC hearing aids. Furthermore, mild and moderate hearing losses share the same physiological causes (e.g., aging and noise exposure) and are fit with the same types of hearing aids.

MYTH: Patients should see a doctor because they might have more serious health problems.

- In 2016, the FDA announced that it would no longer enforce requirement for medical evaluation prior to hearing aid purchase, stating, "the medical evaluation requirement does not appear to provide any meaningful benefits to hearing-impaired adults."
- As far back as 1977, the FDA commissioner noted that, "the number of persons who will in fact require medical or surgical treatment is relatively small compared to the number of individuals who will benefit from amplification."[3]
- The relative number of people with serious ear disease is small. Even Hearing Industries Association (HIA) reports that only 4 percent of people seeking hearing aids have a medical condition that would trigger medical intervention (Shaw, 2016). Finally, many of the conditions that would trigger a medical referral by a dispenser could be self-identified through a questionnaire or because red flag conditions are readily identifiable, such as sudden onset hearing loss in one or both ears, ear pain, discharge from the ear, dizziness.

MYTH: Patients should see an audiologist because they benefit from all the other services.

- According to the Academy of Doctors of Audiology, there is no evidence that a required medical evaluation improves outcomes. In fact, in 2016, the FDA announced it would no longer enforce the requirement that individuals 18 and over receive a medical evaluation or sign a waiver prior to purchasing most hearing aids.[4]

MYTH: Consumers will buy these devices and then they won't work, and then those consumers will feel cheated.

- The Hearing Loss Association of America (HLAA) has a great resource for consumers, which outlines the state laws for hearing aid returns: http://www.hearingloss.org/sites/default/files/docs/Consumer_Protection_Laws.pdf. Most states have specifically addressed the "trial period" and returns. Most states also have general consumer protections that allow them to return products—consumers will have recourse in the OTC market.

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MYTH: This bill will undermine state licensing.

- The bill is narrowly tailored to clear the path for OTC sales, without affecting other laws and consumer protections. For example, the rules requiring a license before a provider can test someone's hearing would remain in place. Other rules on the sale hearing aids, like the common state rule requiring sellers offer a free return policy for a certain period of time, would continue to be applicable an OTC hearing aid.

MYTH: OTC hearing aids could be a risk to children.

- Mail order and Internet hearing aids have been available for decades. Other unregulated devices that amplify sound, such as personal sound amplification products (PSAPs), are also widely available. There is no research that exists that would indicate a pattern of attempts by children to use these devices. Nor are there indications of any pattern of adults obtaining adult hearing aids for use in children.
- Medicaid covers hearing aid services as part of EPSDT (Early and Periodic, Screening, Diagnosis, and Treatment). States must provide to Medicaid beneficiaries under age 21 hearing services, including appropriate screening, diagnostic, and treatment, including hearing aids. Specifically, EPSDT covers the following medically necessary audiological services for children who are at risk for hearing impairment: audiological assessments; hearing aid evaluation; and medically necessary hearing aid services, including hearing aids and hearing aid accessories and services.
- Just as with other OTC medications, warning labels should include contra indications for adult hearing aids for children.

MYTH: Previous attempts at OTC hearing aids, like in Japan and Colorado, didn't work.

- Colorado decided to de-regulate hearing aids in the 1980s; innovation has changed since then and hearing aids should keep pace.
- Furthermore, after Colorado's regulation change, an influx of consumer complaints followed. A 1995 legislative review committee found "the remedies provided by the Consumer Protection Act are more applicable to fraudulent business transactions than is competency based licensing." The Colorado experiment showed that a lack of enforcement of consumer protection laws caused the complaints.
- The Japanese market has low penetration and low satisfaction rates because it is different in complex ways from the U.S. market. It is true that Japan has no licensure requirements for hearing aid technicians. But to attribute the very low penetration of hearing aids in Japan solely to regulatory policy is to ignore the many other factors that are arguably more important to the reluctance of people in Japan to buy or to be seen wearing hearing aids (e.g. hearing loss is regarded as a disability and hearing aids are provided only for severely-impaired, only an astonishingly low 13% of people ever get a hearing aid recommendation from their doctor).

MYTH: There hasn't been any public input. We should slow down and just do a study.

- In 2013, the FDA accepted public comment on the draft guidance regarding Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products (which this H.R. 1652 would require FDA to finalize).
- Additionally, the FDA held a public workshop on April 21, 2016 to examine the appropriate level of Good Manufacturing Practices (GMPs) regulation to ensure the safety and effectiveness of air-conduction hearing aid devices.
- The PCAST and NASEM studies already provide reliable information and data.